§ 181.33

200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

- (1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food-contact surface—0.003 milligram/square inch when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.
- (2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food-contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.
- (3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(c) Acrylonitrile monomer may present a hazard to health when ingested. Accordingly, any food-contact article containing acrylonitrile copolymers or resins that yield acrylonitrile monomer in excess of that amount provided for in paragraph (b) of this section shall be deemed to be adulterated in violation of section 402 of the Act.

[42 FR 14638, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982; 54 FR 24899, June 12, 1989]

§181.33 Sodium nitrate and potassium nitrate.

Sodium nitrate and potassium nitrate are subject to prior sanctions issued by the U.S. Department of Agriculture for use as sources of nitrite, with or without sodium or potassium

nitrite, in the production of cured red meat products and cured poultry products.

[48 FR 1705, Jan. 14, 1983]

§181.34 Sodium nitrite and potassium nitrite.

Sodium nitrite and potassium nitrite are subject to prior sanctions issued by the U.S. Department of Agriculture for use as color fixatives and preservative agents, with or without sodium or potassium nitrate, in the curing of red meat and poultry products.

[48 FR 1705, Jan. 14, 1983]

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

182.1 Substances that are generally recognized as safe.

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182.1045 Glutamic acid.

182.1047 Glutamic acid hydrochloride.

182.1057 Hydrochloric acid.

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182.1125 Aluminum sulfate.

182.1127 Aluminum ammonium sulfate.

182.1129 Aluminum potassium sulfate. 182.1131 Aluminum sodium sulfate.

182.1180 Caffeine.

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182.1235 Caramel.

182.1320 Glycerin.

182.1480 Methylcellulose. 182.1500 Monoammonium glutamate.

182.1516 Monopotassium glutamate.

182.1711	Silica aerogel.	182.8159	Biotin.
182.1745	Sodium carboxymethylcellulose.	182.8217	Calcium phosphate.
182.1748	Sodium caseinate.	182.8223	Calcium pyrophosphate.
182.1778	Sodium phosphate.	182.8250	Choline bitartrate.
182.1781	Sodium aluminum phosphate.	182.8252	Choline chloride.
182.1810	Sodium tripolyphosphate.	182.8778	Sodium phosphate.
_		182.8890	Tocopherols.
Si	ubpart C—Anticaking Agents	182.8892	α-Tocopherol acetate.
182.2122	Aluminum calcium silicate.	182.8985	Zinc chloride.
182.2227	Calcium silicate.	182.8988	Zinc gluconate.
182.2437	Magnesium silicate.	182.8991	Zinc oxide.
182.2727	Sodium aluminosilicate.	182.8994	Zinc stearate.
182.2729	Sodium calcium aluminosilicate.	182.8997	Zinc sulfate.
hydrated.		Arrest o Dreet 1 1 C C 001 040 040 071	
182.2906 Tricalcium silicate.		AUTHO	PRITY: 21 U.S.C. 321, 342, 348, 371.

Subpart D—Chemical Preservatives

182.3013	Ascorbic acid.
182.3041	Erythorbic acid.
182.3089	Sorbic acid.
182.3109	Thiodipropionic acid.
182.3149	Ascorbyl palmitate.
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182.3189	Calcium ascorbate.
182.3225	Calcium sorbate.
182.3280	Dilauryl thiodipropionate.
182.3616	Potassium bisulfite.
182.3637	Potassium metabisulfite.
182.3640	Potassium sorbate.
182.3731	Sodium ascorbate.
182.3739	Sodium bisulfite.
182.3766	Sodium metabisulfite.
182.3795	Sodium sorbate.
182.3798	Sodium sulfite.
182.3862	Sulfur dioxide.
182.3890	Tocopherols.

Subpart E—Emulsifying Agents [Reserved]

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182.6197	Calcium diacetate.
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182.6215	Monobasic calcium phosphate.
182.6285	Dipotassium phosphate.
182.6290	Disodium phosphate.
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182.6760	Sodium hexametaphosphate.
182.6769	Sodium metaphosphate.
182.6778	Sodium phosphate.
182.6787	Sodium pyrophosphate.

182.6789 Tetra sodium pyrophosphate.

182.6085 Sodium acid phosphate.

Sodium tripolyphosphate. Subpart H—Stabilizers

 $182.7255 \quad \hbox{Chondrus extract.}$

Subpart I—Nutrients

182.8013 Ascorbic acid.

182.6810

Subpart A—General Provisions

otherwise noted.

Source: 42 FR 14640, Mar. 15, 1977, unless

§182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generaly recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular

grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

- (c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.
- (d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been revaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g.,

"affirmed as GRAS" under part 184 or 186 of this chapter; "food additive regulation" under parts 170 through 180 of this chapter; "interim food additive regulation" under part 180 of this chapter; or "prohibited from use in food" under part 189 of this chapter.

[42 FR 14640, Mar. 15, 1977, as amended at 53 FR 44875, Nov. 7, 1988]

§ 182.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa herb and seed	. Medicago sativa L.
Allspice	
Ambrette seed	
Angelica	
Angelica root	1 0
Angelica seed	
Angostura (cusparia bark)	
Anise	
Anise star	F
Balm (lemon balm)	
Basil, bush	
Basil, sweet	
Bay	
Calendula	
Camomile (chamomile), English or Roman	
Camomile (chamomile), German or Hungarian	
Capers	
Capsicum	
Caraway	
Caraway, black (black cumin)	
Cardamom (cardamon)	
Cassia, Chinese	
Cassia, Padang or Batavia	
Cassia, Saigon	
Cayenne pepper	. Capsicum frutescens L. or Capsicum annuum L.
Celery seed	. Apium graveolens L.
Chervil	. Anthriscus cerefolium (L.) Hoffm.
Chives	. Allium schoenoprasum L.
Cinnamon, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon, Chinese	
Cinnamon, Saigon	Cinnamomum loureirii Nees.
Clary (clary sage)	Salvia sclarea L.
Clover	. Trifolium spp.
Coriander	. Coriandrum sativum L.
Cumin (cummin)	. Cuminum cyminum L.
Cumin, black (black caraway)	Nigella sativa L.
Elder flowers	
Fennel, common	
Fennel, sweet (finocchio, Florence fennel)	
Fenugreek	
Galanga (galangal)	
Geranium	
Ginger	
Grains of paradise	
Horehound (hoarhound)	
Horseradish	
Hyssop	
Lavender	
Laveriuer	
Linden flowers	. Tilia spp.

Common name	Botanical name of plant source
Marigold, pot	Calendula officinalis L.
Marjoram, pot	Majorana onites (L.) Benth.
Marjoram, sweet	Majorana hortensis Moench.
Mustard, black or brown	Brassica nigra (L.) Koch.
Mustard, brown	Brassica juncea (L.) Coss.
Mustard, white or yellow	Brassica hirta Moench.
Nutmeg	Myristica fragrans Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan).	Lippia spp.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, cayenne	Capsicum frutescens L. or Capsicum annuum L.
Pepper, red	Do.
Pepper, white	Piper nigrum L.
Peppermint	Mentha piperita L.
Poppy seed	Papayer somniferum L.
Pot marigold	Calendula officinalis L.
Pot marjoram	Majorana onites (L.) Benth.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L. (Satureja).
Savory, winter	Satureia montana L. (Satureja).
Sesame	Sesamum indicum L.
Spearmint	Mentha spicata L.
Star anise	Illicium verum Hook. f.
Tarragon	Artemisia dracunculus L.
Thyme	Thymus vulgaris L.
Thyme, wild or creeping	Thymus serpyllum L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Zedoary	Curcuma zedoaria Rosc.

 $[42~\mathrm{FR}$ 14640, Mar. 15, 1977, as amended at 43 FR 3705, Jan. 27, 1978; 44 FR 3963, Jan. 19, 1979; 50 FR 21044, May 22, 1985; 61 FR 14246, Apr. 1, 1996]

§ 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solventfree), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.
Camomile (chamomile) flowers, Hungarian	Matricaria chamomilla L.
Camomile (chamomile) flowers, Roman or English	Anthemis nobilis L.
Cananga	Cananga odorata Hook. f. and Thoms.

Common name	Botanical name of plant source
Capsicum	Capsicum frutescens L. and Capsicum annuum L.
Caraway	Carum carvi L.
Cardamom seed (cardamon)	Elettaria cardamomum Maton.
Carob bean	Ceratonia siliqua L.
Carrot	Daucus carota L.
Cascarilla bark	Croton eluteria Benn.
Cassia bark, Chinese	Cinnamomum cassia Blume. Cinnamomum burmanni Blume.
Cassia bark, Saigon	Cinnamomum loureirii Nees.
Celery seed	Apium graveolens L.
Cherry, wild, bark	Prunus serotina Ehrh.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Cinnamon bark, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese	Cinnamomum cassia Blume. Cinnamomum loureirii Nees.
Cinnamon bark, Saigon	Cinnamomum zevlanicum Nees.
Cinnamon leaf, Chinese	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon	Cinnamomum loureirii Nees.
Citronella	Cymbopogon nardus Rendle.
Citrus peels	Citrus spp.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Coca (decocainized)	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee	Coffea spp. Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Curacao orange peel (orange, bitter peel)	Citrus aurantium L.
Cusparia bark	Galipea officinalis Hancock.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra I.
Estragole (esdragol, esdragon, tarragon)	Artemisia dracunculus L.
Estragon (tarragon)	Do. Foeniculum vulgare Mill.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Geranium, East Indian	Cymbopogon martini Stapf.
Geranium, rose	Pelargonium graveolens L'Her.
Ginger	Zingiber officinale Rosc.
Grapefruit	Citrus paradisi Macf.
Guava	Psidium spp.
Hickory bark Horehound (hoarhound)	Carya spp.
Hops	Marrubium vulgare L. Humulus lupulus L.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.
Jasmine	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries)	Juniperus communis L.
Kola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel berries	Laurus nobilis L.
Laurel leaves	Laurus spp.
Lavender Lavender, spike	Lavandula officinalis Chaix. Lavandula latifolia Vill.
Lavender, spike	Hybrids between Lavandula officinalis Chaix and Lavandula latifolin Vill.
Lemon	Citrus limon (L.) Burm. f.
Lemon balm (see balm).	
Lemon grass	Cymbopogon citratus DC. and Cymbopogon lexuosus Stapf.
Lemon peel	Citrus limon (L.) Burm. f.
Lime	Citrus aurantifolia Swingle.
Linden flowers	Tilia spp.
Locust bean	Ceratonia siliqua L,
Lupulin	Humulus lupulus L.
Mace Mandarin	Myristica fragrans Houtt. Citrus reticulata Blanco.
Marjoram, sweet	Majorana hortensis Moench.
Maté	llex paraguariensis St. Hil.
Melissa (see balm).	
	1
Menthol	Mentha spp.

Common name	Botanical name of plant source
Molasses (extract)	Saccarum officinarum L.
Mustard	Brassica spp.
Naringin	Citrus paradisi Macf.
Neroli, bigarade	Citrus aurantium L.
Nutmeg	Myristica fragrans Houtt.
Onion	Allium cepa L.
Orange, bitter, flowers	Citrus aurantium L.
	Do
Orange, bitter, peel	20.
Orange leaf	Citrus sinensis (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	Origanum spp.
Palmarosa	Cymbopogon martini Stapf.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, white	Do.
Peppermint	Mentha piperita L.
Peruvian balsam	Myroxylon pereirae Klotzsch.
Petitgrain	Citrus aurantium L.
Petitgrain lemon	Citrus limon (L.) Burm. f.
Petitgrain mandarin or tangerine	Citrus reticulata Blanco.
Pimenta	Pimenta officinalis Lindl.
Pimenta leaf	Pimenta officinalis Lindi.
Pipsissewa leaves	Chimaphila umbellata Nutt.
Pomegranate	Punica granatum L.
Prickly ash bark	Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clav
Rose absolute	herculis L., Rosa centifolia L., Rosa damascena Mill., Rosa gallica l and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
	Do.
Rose fruit (hips)	20.
Rose geranium	Pelargonium graveolens L'Her.
Rose leaves	Rosa spp.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Sage, Spanish	Salvia lavandulaefolia Vahl.
St. John's bread	Ceratonia siliqua L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Schinus molle	Schinus molle L.
Sloe berries (blackthorn berries)	Prunus spinosa L.
Spearmint	Mentha spirata L.
Spike lavender	Lavandula latifolia Vill.
Tamarind	Tamarindus indica L.
Tangerine	Citrus reticulata Blanco.
Tarragon	Artemisia dracunculus L.
Tea	Thea sinensis L.
Thyme	Thymus vulgaris L. and Thymus zygis var. gracilis Boiss.
Thyme, white	Do.
Thyme, wild or creeping	Thymus serpyllum L.
Triticum (see dog grass).	' ' '
Tuberose	Polianthes tuberosa L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Violet flowers	Viola odorata L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	Prunus serotina Ehrh.
Ylang-ylang	Cananga odorata Hook. f. and Thoms.
riang-yiang	

 $[42~\mathrm{FR}$ 14640, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 47 FR 29953, July 9, 1982; 48 FR 51613, Nov. 10, 1983; 50 FR 21043, 21044, May 22, 1985]

§ 182.40 Natural extractives (solventfree) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices,

seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Apricot kernel (persic oil)	Prunus armeniaca L. Prunus persica Sieb. et Zucc. Arachis hypogaea L.
Quince seed	Cydonia oblonga Miller.

[42 FR 14640, Mar. 15, 1977, as amended at 47 FR 47375, Oct. 26, 1982]

§ 182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural ex-

tracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Derivation
Ambergris Castoreum Civet (zibeth, zibet, zibetum) Cognac oil, white and green Musk (Tonquin musk)	Castor fiber L. and C. canadensis Kuhl. Civet cats, Viverra civetta Schreber and Viverra zibetha Schreber. Ethyl oenanthate, so-called.

§ 182.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Acetaldehyde (ethanal).

Acetoin (acetyl methylcarbinol).

Anethole (parapropenyl anisole).

Benzaldehyde (benzoic aldehyde).

 $N ext{-Butyric}$ acid (butanoic acid).

d- or l-Carvone (carvol).

Cinnamaldehyde (cinnamic aldehyde).

Citral (2,6-dimethyloctadien-2,6-al-8, geranial, neral).

Decanal (N-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).

Ethyl acetate.

Ethyl butyrate.

3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).

Ethyl vanillin.

Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-ol).

Geranyl acetate (geraniol acetate).

Limonene (d-, l-, and dl-).

Linalool (linalol, 3,7-dimethyl-1,6-octadien-3- \it{ol}).

Linalyl acetate (bergamol).

Methyl anthranilate (methyl-2-aminobenzoate).

Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).

Vanillin.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 47724, Oct. 17, 1978; 44 FR 3963, Jan. 19, 1979; 44 FR 20656, Apr. 6, 1979; 48 FR 51907, Nov. 15, 1983; 54 FR 7402, Feb. 21, 1989]

§ 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

Substances migrating to food from cotton and cotton fabrics used in dry food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Beef tallow.

Carboxymethylcellulose.

Coconut oil, refined.

Cornstarch.

Lard.

Lard. Lard oil.

Oleic acid.

Peanut oil.

Potato starch.

Sodium acetate. Sodium chloride.

Sodium silicate.
Sodium tripolyphosphate.
Soybean oil (hydrogenated).
Talc.
Tallow (hydrogenated).
Tallow flakes.
Tapioca starch.
Tetrasodium pyrophosphate.
Wheat starch.
Zinc chloride.

 $[42\ \mathrm{FR}\ 14640,\ \mathrm{Mar}.\ 15,\ 1977,\ \mathrm{as}\ \mathrm{amended}\ \mathrm{at}\ 43\ \mathrm{FR}\ 11698,\ \mathrm{Mar}.\ 21,\ 1978;\ 44\ \mathrm{FR}\ 28323,\ \mathrm{May}\ 15,\ 1979;\ 45\ \mathrm{FR}\ 6085,\ \mathrm{Jan}.\ 25,\ 1980;\ 47\ \mathrm{FR}\ 27807,\ 27814,\ \mathrm{June}\ 25,\ 1982;\ 48\ \mathrm{FR}\ 51150,\ \mathrm{Nov}.\ 7,\ 1983;\ 48\ \mathrm{FR}\ 51616,\ \mathrm{Nov}.\ 10,\ 1983;\ 48\ \mathrm{FR}\ 51999,\ \mathrm{Nov}.\ 15,\ 1983;\ 48\ \mathrm{FR}\ 52441,\ 52443,\ 52445,\ 52446,\ \mathrm{Nov}.\ 18,\ 1983;\ 51\ \mathrm{FR}\ 16830,\ \mathrm{May}\ 7,\ 1986;\ 51\ \mathrm{FR}\ 27171,\ \mathrm{July}\ 30,\ 1986;\ 60\ \mathrm{FR}\ 62208,\ \mathrm{Dec.}\ 5,\ 1995]$

§ 182.90 Substances migrating to food from paper and paperboard products.

Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Alum (double sulfate of aluminum and ammonium potassium, or sodium).

Aluminum hydroxide. Aluminum oleate.

Aluminum palmitate.

Casein.

Cellulose acetate.

Cornstarch.

Diatomaceous earth filler.

Ethyl cellulose.

Ethyl vanillin.

Glycerin.

Oleic acid.

Potassium sorbate.

Silicon dioxides.

Sodium aluminate.

Sodium chloride.

Sodium hydrogulfite

Sodium hydrosulfite.

Sodium phosphoaluminate.

Sodium silicate.

Sodium sorbate.

Sodium tripolyphosphate.

Sorbitol.

Soy protein, isolated.

Starch, acid modified. Starch, pregelatinized.

Starch, unmodified.

Talc.

Vanillin.

Zinc hydrosulfite.

Zinc nydrosumite Zinc sulfate.

[42 FR 14640, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §182.90, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at www.govinfo.gov.

§ 182.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.910 and 40 CFR 180.920, which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

[76 FR 59249, Sept. 26, 2011]

Subpart B—Multiple Purpose GRAS Food Substances

§ 182.1045 Glutamic acid.

- (a) Product. Glutamic acid.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1047 Glutamic acid hydrochloride.

- (a) *Product*. Glutamic acid hydrochloride.
 - (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1057 Hydrochloric acid.

- (a) Product. Hydrochloric acid.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing practice.

§ 182.1073 Phosphoric acid.

- (a) Product. Phosphoric acid.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.1087 Sodium acid pyrophosphate.

(a) *Product*. Sodium acid

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.1125 Aluminum sulfate.

- (a) Product. Aluminum sulfate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

\$182.1127 Aluminum ammonium sulfate.

- (a) *Product*. Aluminum ammonium sulfate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1129 Aluminum potassium sulfate.

- (a) *Product*. Aluminum potassium sulfate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1131 Aluminum sodium sulfate.

- (a) *Product.* Aluminum sodium sulfate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.1180 Caffeine.

- (a) Product. Caffeine.
- (b) Tolerance. 0.02 percent.
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

§182.1217 Calcium phosphate.

- (a) *Product*. Calcium phosphate (mono-, di-, and tribasic).
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1235 Caramel.

- (a) Product. Caramel.
- (b) Conditions of use. This substance is generally recognized as safe when

used in accordance with good manufacturing practice.

§182.1320 Glycerin.

- (a) Product. Glycerin.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1480 Methylcellulose.

- (a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1500 Monoammonium glutamate.

- (a) *Product*. Monoammonium glutamate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.1516 Monopotassium glutamate.

- (a) Product. Monopotassium glutamate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1711 Silica aerogel.

- (a) *Product*. Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.
 - (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used as a component of an anti-foaming agent in accordance with good manufacturing practice.

§ 182.1745 Sodium carboxymethylcellulose.

(a) Product. Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per

anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25 $^{\circ}\mathrm{C}.$

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1748 Sodium caseinate.

- (a) Product. Sodium caseinate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1778 Sodium phosphate.

- (a) *Product*. Sodium phosphate (mono-, di-, and tribasic).
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1781 Sodium aluminum phosphate.

- (a) Product. Sodium aluminum phosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.1810 Sodium tripolyphosphate.

- (a) *Product*. Sodium tripolyphosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart C—Anticaking Agents

§182.2122 Aluminum calcium silicate.

- (a) Product. Aluminum calcium silicate.
 - (b) Tolerance. 2 percent.
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§182.2227 Calcium silicate.

- (a) Product. Calcium silicate.
- (b) Tolerance. 2 percent and 5 percent.
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used at levels not

exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing practice.

§ 182.2437 Magnesium silicate.

- (a) Product. Magnesium silicate.
- (b) *Tolerance*. 2 percent.
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2727 Sodium aluminosilicate.

- (a) *Product*. Sodium aluminosilicate (sodium silicoaluminate).
- (b) *Tolerance*. This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2729 Sodium calcium aluminosilicate, hydrated.

- (a) Product. Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).
- (b) *Tolerance*. This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2906 Tricalcium silicate.

- (a) Product. Tricalcium silicate.
- (b) Tolerance. 2 percent.
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

Subpart D—Chemical Preservatives

§182.3013 Ascorbic acid.

- (a) Product. Ascorbic acid.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3041 Erythorbic acid.

- (a) Product. Erythorbic acid.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.3089 Sorbic acid.

- (a) Product. Sorbic acid.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3109 Thiodipropionic acid.

- (a) Product. Thiodipropionic acid.
- (b) Tolerance. This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§182.3149 Ascorbyl palmitate.

- (a) Product. Ascorbyl palmitate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3169 Butylated hydroxyanisole.

- (a) *Product*. Butylated hydroxyanisole.
- (b) Tolerance. This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3173 Butylated hydroxytoluene.

- (a) *Product*. Butylated hydroxytoluene.
- (b) Tolerance. This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§182.3189 Calcium ascorbate.

- (a) Product. Calcium ascorbate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3225 Calcium sorbate.

(a) Product. Calcium sorbate.

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3280 Dilauryl thiodipropionate.

- (a) *Product*. Dilauryl thiodipropionate.
- (b) Tolerance. This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§182.3616 Potassium bisulfite.

- (a) Product. Potassium bisulfite.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B₁; on fruits and vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3637 Potassium metabisulfite.

- (a) Product. Potassium metabisulfite.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1 ; on fruits and vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3640 Potassium sorbate.

- (a) Product. Potassium sorbate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3731 Sodium ascorbate.

- (a) Product. Sodium ascorbate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3739 Sodium bisulfite.

- (a) Product. Sodium bisulfite.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1 ; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3766 Sodium metabisulfite.

- (a) Product. Sodium metabisulfite.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1 ; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3795 Sodium sorbate.

- (a) Product. Sodium sorbate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.3798 Sodium sulfite.

- (a) Product. Sodium sulfite.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1 ; on fruits or vegetables in-

tended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3862 Sulfur dioxide.

- (a) Product. Sulfur dioxide.
- (b) [Reserved]
- (c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1 ; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3890 Tocopherols.

- (a) Product. Tocopherols.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart E—Emulsifying Agents [Reserved]

Subpart F—Dietary Supplements [Reserved]

Subpart G—Sequestrants 1

§ 182.6085 Sodium acid phosphate.

- (a) Product. Sodium acid phosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6197 Calcium diacetate.

- (a) Product. Calcium diacetate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

¹For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 182.6203 Calcium hexametaphosphate.

- (a) Product. Calcium hexametaphosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6215 Monobasic calcium phosphate.

- (a) *Product*. Monobasic calcium phosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6285 Dipotassium phosphate.

- (a) Product. Dipotassium phosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6290 Disodium phosphate.

- (a) Product. Disodium phosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.6757 Sodium gluconate.

- (a) Product. Sodium gluconate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6760 Sodium hexametaphosphate.

- (a) Product. Sodium hexametaphosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6769 Sodium metaphosphate.

- (a) Product. Sodium metaphosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.6778 Sodium phosphate.

(a) *Product*. Sodium phosphate (mono-, di-, and tribasic).

(b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6787 Sodium pyrophosphate.

- (a) Product. Sodium pyrophosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6789 Tetra sodium pyrophosphate.

- (a) *Product*. Tetra sodium pyrophosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6810 Sodium tripolyphosphate.

- (a) *Product*. Sodium tripolyphosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart H—Stabilizers

§ 182.7255 Chondrus extract.

- (a) *Product*. Chondrus extract (carrageenin).
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart I—Nutrients

Source: 45 FR 58838, Sept. 5, 1980, unless otherwise noted.

§ 182.8013 Ascorbic acid.

- (a) Product. Ascorbic acid.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8159 Biotin.

- (a) Product. Biotin.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8217 Calcium phosphate.

- (a) *Product*. Calcium phosphate (mono-, di-, and tribasic).
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8223 Calcium pyrophosphate.

- (a) *Product*. Calcium pyrophosphate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8250 Choline bitartrate.

- (a) Product. Choline bitartrate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8252 Choline chloride.

- (a) Product. Choline chloride.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8778 Sodium phosphate.

- (a) *Product*. Sodium phosphate (mono-, di-, and tribasic).
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§182.8890 Tocopherols.

- (a) Product. Tocopherols.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8892 α -Tocopherol acetate.

- (a) Product. α -Tocopherol acetate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8985 Zinc chloride.

- (a) Product. Zinc chloride.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8988 Zinc gluconate.

- (a) Product. Zinc gluconate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8991 Zinc oxide.

- (a) Product. Zinc oxide.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8994 Zinc stearate.

- (a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8997 Zinc sulfate.

- (a) Product. Zinc sulfate.
- (b) Conditions of use. This substance is generally recognized as safe when used in accordance with good manufacturing practice.

PART 184—DIRECT FOOD SUB-STANCES AFFIRMED AS GEN-ERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

Subpart B—Listing of Specific Substances Affirmed as GRAS

184.1005 Acetic acid.

184.1007 Aconitic acid.

184.1009 Adipic acid.

184.1011 Alginic acid.

184.1012 α-Amylase enzyme preparation

from Bacillus stearothermophilus.

184.1021 Benzoic acid.

184.1024 Bromelain.

184.1025 Caprylic acid.

184.1027 Mixed carbohydrase and protease enzyme product.

184.1033 Citric acid.

184.1034 Catalase (bovine liver).

184.1061 Lactic acid.

184.1063 Enzyme-modified lecithin.

184.1065 Linoleic acid.

184.1069 Malic acid.